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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,048	08/09/1999	NAPHTALI SAVION	0744/077	4662

27557 7590 07/24/2003

BLANK ROME LLP  
600 NEW HAMPSHIRE AVENUE, N.W.  
WASHINGTON, DC 20037

EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/341,048

Applicant(s)

SAVION ET AL.

Examiner

Zohreh Fay

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 108-140 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 108-111, 116, 117 and 133-140 is/are rejected.
- 7) ☒ Claim(s) 112-115 and 118-132 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Claims 108-40 are presented for examination.

The remarks filed on February 28, 2003 have been received and entered.

Claims 108-111, 116, 117, 133, 137 and 138 are rejected under 35 U.S.C. 102 (b) as being anticipated by European Patent Application 0 312 814 for the reasons set forth on page 2 of the office action of December 2, 2002.

Claims 133, 135, 136, 139 and 140 are rejected under 35 U.S.C. 102 (b) as being anticipated by Levine et al. for the reasons set forth on page 2 of the office action of December 2, 2002.

Claim 134 is rejected under 35 U.S.C. 102 (b) as being anticipated by Davis et al. Davis et al. Teach the use of Lipofundin and Intralipid in a pharmaceutical emulsion formulation. See page 4, paragraphe 13. The above reference makes clear that the claimed composition is old and well known.

Claims 112-115 and 118-132 are objected to as being dependent on a rejected claim.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. Applicant's arguments regarding the composition claims are not well taken. The claimed components have been previously used in a pharmaceutical formulation. The new use of an old composition does not create a patentably distinct composition. Applicant's arguments regarding the method of use claims are not also well taken. Claim 111 is directed to dry eye syndrome. Claim 108 is also directed to "systemic diseases causing damage to corneal epithelial" which Sjorgren syndrome (dry eye) is one of the conditions covered under such diseases.

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Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, the above rejections are considered to be proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (703) 308-4604. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Z.F  
July 15, 2003

ZOHREH FAY  
PRIMARY EXAMINER  
GROUP 1200

*Zohreh Fay*